

Listing of claims

This listing of claims will replace all prior versions and listings of the claims in the application.

Claims 1-20 (Cancelled).

21. (Currently Amended) A directly compressible tablet adapted to disintegrate in the mouth on contact with saliva in less than 30 seconds ~~and, forming an easy-to-swallow suspension and having a friability of less than 1%, said tablet obtained by direct compression and~~ comprising a dry mixture of coated microcrystals or microgranules of an active substance and excipients including ~~at least one~~ disintegrating agent, a soluble agent with binding properties, and a lubricating agent in powder form, wherein: ~~(a) the lubricating agent is in powder form; (b) more than half of the lubricating agent is distributed on the tablet surface; (c) the tablet has a friability of less than 1%.~~

22. (Previously Presented) Tablet in accordance with Claim 21, wherein a largest dimension of the tablet is greater than 5 mm.

23. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent is a pharmaceutically acceptable lubricating agent having a melting point of at least 35°C.

24. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent is a member selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

25. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent is magnesium stearate.

26. (Previously Presented) Tablet in accordance with Claim 21, wherein a quantity of lubricating agent is in a range 0.2 to

10 parts per 1000 based on a weight of lubricating agent per total weight of the tablet.

27. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent has a particle size distribution less than 30 microns, such that constituent particles of the lubricating agent adhere to a surface when the lubricating agent is sprayed against the surface.

28. (Previously Presented) Tablet in accordance with Claim 21, wherein the disintegrating agent is a member selected from the group consisting of cross-linked sodium carboxymethylcellulose, crospovidone and their mixtures.

29. (Previously Presented) Tablet in accordance with Claim 21, wherein the excipients include a permeabilising agent, a solubilising agent, sweeteners, flavors and colorings.

30. (Previously Presented) Tablet in accordance with Claim 21, wherein the tablet is adapted to withstand being packaged in and delivered from blisters composed entirely of aluminum, said blisters optionally including a cover of a plastic material which is to be torn off before opening.

31. (Currently Amended) Process for the production of a tablet in accordance with Claim 21, wherein the process comprises the following steps:

- choosing, firstly, an active substance in a form of coated microcrystals or microgranules, and secondly, a set of excipients including a disintegrating agent, a soluble agent with binding properties, and also a lubricating agent in powder form;

- dry mixing the active substance and the excipients to form a mixture, provided that more than half of the lubricating agent is not included in the mixture;

- applying more than half of the lubricating agent onto walls surrounding a cavity of a compression device;

- feeding a quantity of the mixture necessary to form a tablet into the cavity of the compression device within which the mixture is to be compressed and onto the walls of which more than half of the lubricating agent has been applied in advance;

- compressing the mixture and ejecting the tablet formed.

32. (Previously Presented) Process in accordance with Claim 31, wherein compression forces are in a compression force range from 3 kN to 50 kN.

33. (Previously Presented) Tablet according to Claim 21, wherein the friability of the tablet is less than 0.5%.

34. (Previously Presented) Tablet in accordance with Claim 22, wherein the largest dimension of the tablet is greater than 17 mm.

35. (Previously Presented) Tablet in accordance with Claim 23, wherein the lubricating agent has a melting point higher than 50°C.

36. (Previously Presented) Tablet in accordance with Claim 26, wherein the quantity of lubricating agent is in the range of 3 to 6 parts per 1000.

37. (Previously Presented) Tablet in accordance with Claim 27, wherein the lubricating agent has a particle size distribution less than 10 microns.

38. (Previously Presented) Process in accordance with Claim 32, wherein the compression force range is 4 kN to 40 kN.

39. (Previously Presented) Process in accordance with Claim 38, wherein the compression force range is 5 kN to 25 kN.

40. (Previously Presented) Process in accordance with Claim 31, wherein none of the lubricating agent is dry mixed with the active substance and other excipients to form a mixture, and all of the lubricating agent is applied onto the walls surrounding the cavity of the compression device, such that all

of the lubricating agent of the tablet is distributed on an outer surface of the tablet.

41. (Previously Presented) Tablet in accordance with Claim 21, wherein all of the lubricating agent of the tablet is distributed on an outer surface of the tablet.

42. (New) Process in accordance with claim 31, wherein the lubricating agent is a member selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

43. (New) Tablet in accordance with Claim 31, wherein the disintegrating agent is a member selected from the group consisting of cross-linked sodium carboxymethylcellulose, crospovidone and their mixtures.

44. (New) Process in accordance with claim 31, wherein the excipients include a permeabilising agent, a solubilising agent, sweeteners, flavors and colorings.

45. (New) Process for reducing the friability of the directly compressible tablet comprising the step of spraying a lubricating agent on the surface of compression punches in order that more than half of the lubricating agent is distributed on the tablet surface, said tablet comprising a dry mixture of coated microcrystals or microgranules of an active substance and excipients including at least a disintegrating agent, a soluble agent with binding properties, and a lubricating agent in powder form.

46. (New) Process in accordance with Claim 45, wherein the lubricating agent is a member selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

Application No. 09/914,544
Amendment of 8/10/07
In Response to Office Action of 4/12/07

47. (New) Tablet in accordance with Claim 45, wherein the disintegrating agent is a member selected from the group consisting of cross-linked sodium carboxymethylcellulose, crospovidone and their mixtures.